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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* PETER ZHU,
and SZU-MIN LIN

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Appeal 2008-3156
Application 09/810,872
Technology Center 1700

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Decided: September 30, 2008

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Before EDWARD C. KIMLIN, CHUNG K. PAK, and
KAREN M. HASTINGS, *Administrative Patent Judges*.

HASTINGS, *Administrative Patent Judge*.

## DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134(a) from the Examiner's final rejection of claims 1-7, 10-14, 30, 32, and 33. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

## I. BACKGROUND

The invention relates to a method for determining a point of interest of an aldehyde in a test sample. Independent claims 1 and 32 are illustrative:

1. A method of determining the presence of a point of interest of an aldehyde in a test sample using a first reactant capable of reacting with a carbonyl group of the aldehyde and a second reactant comprising a compound having an amino group and which is capable of reacting with the aldehyde to produce a color change, the method comprising the steps of:

in a first reacting step, in the presence of the second reactant reacting the aldehyde in the test sample with an amount of the first reactant sufficient to react with the aldehyde to the point of interest;

in a second reacting step, reacting the second reactant with any remaining aldehyde in the test sample to produce a first color; and

determining the presence of an excess of aldehyde in the test sample to the point of interest by observation of a final color of the test sample.

32. A method of determining the presence of a point of interest of OPA in a test sample comprising the steps of:

reacting the OPA in the test sample with an amount of a salt of bisulfite in a first reacting step, wherein said amount is sufficient to react with the OPA to the point of interest to produce a first color;

reacting a compound having an amino group with an remaining OPA in the test sample in a second reacting step, the compound being one that reacts with the OPA to produce a second color; and

determining the presence of an excess of OPA in the test sample to the point of interest by observation of a final color of the test sample,

wherein the first reacting step occurs in the presence of the compound having an amino group.

The Examiner relies upon the following prior art as evidence of unpatentability:

| | | |
|---|---|---|
| Opp | 4,471,055 | Sep. 11, 1984 |
| Witonsky | 4,521,376 | Jun. 4, 1985 |
| McAlister | 4,703,763 | Nov. 3, 1987 |
| Wu | 6,436,716 B1 | Aug. 20, 2002 |

Claims 1-7, 10-12, 14 and 30 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Opp.

Claim 13 stands rejected under 103(a) as unpatentable over Opp in view of McAlister[1].

Claims 32 and 33 stand rejected under 103(a) as unpatentable over Witonsky in view of Wu.

Appellants do not separately argue with any reasonable specificity the individual claims in the rejection under 35 U.S.C. § 102 (Br. 4-5). Therefore, we select independent claim 1 to decide this issue on appeal. We will separately address dependent claim 13, as well as independent claim 32, in accordance with Appellants' arguments (Br. 5-6).

[1] We note that Appellants appealed the decision of the Examiner "finally rejecting claims 1-7, 10-14, 30, 32 and 33" (Notice of Appeal filed Dec. 2, 2004). It is readily apparent that the rejection based on the combination of Opp with McAlister is of dependent claim 13, since the substance of claim 13 (i.e., a measuring device having a "liquid impermeable membrane") is addressed by the Examiner in the rejection, and this limitation only appears in claim 13. Claim 14 was included and addressed in the § 102 rejection based on Opp.

## ISSUES ON APPEAL

The issues arising from the contentions of the Appellants and the Examiner are:

1) whether the Appellants have shown that the Examiner reversibly erred in rejecting claims 1-7, 10-12, 14 and 30 as anticipated by Opp, specifically because Opp does not teach that the first reaction step is in the presence of the second reactant as required by claim 1, and further because Opp is not an enabling reference;

2) whether the Appellants have shown that the Examiner reversibly erred in rejecting claim 13 as unpatentable over the combination of Opp and McAlister, specifically because there is no motivation to combine these two references; and,

3) whether the Appellants have shown that the Examiner reversibly erred in rejecting claims 32 and 33 as unpatentable over the combination of Witonsky and Wu, specifically because neither references teaches "the first reacting step occurs in the presence of the compound having an amino group" as claimed in claim 32.

## OPINION

*The 102 Rejection over Opp*

Principles of Law

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 827 (1987).

Inventions disclosed in the applied prior art references enjoy a statutory presumption of validity since the applied prior art references are U.S. patents. 35 U.S.C. § 282 (1999); *In re Spence*, 261 F.2d 244, 246 (CCPA 1958). The enablement requirement under 35 U.S.C. § 112 is a prerequisite to validity. *Cf. Spence,* 261 F.2d at 246. It follows that the prior art is presumed enabling absent clear and convincing evidence to the contrary.

It is also well settled that prior art under 35 U.S.C. § 102(b) must be "enabling", i.e., it "must sufficiently describe the claimed invention to have placed the public in possession of it." *In re Donohue,* 766 F.2d 531, 533 (Fed. Cir. 1985) "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *Id.* A reference is presumed to be enabling and therefore, once the Examiner establishes that the reference teaches each and every limitation of the claimed invention, the burden shifts to the applicants to prove the reference is not enabling. *Chester v. Miller,* 906 F.2d 1574, 1578 (Fed. Cir. 1990); *In re Sasse*, 629 F.2d 675, 681 (CCPA 1980).

Factual Findings

We determine the following Factual Findings (FF) from the record in this appeal. Additional factual findings as needed appear in the analysis portion of the opinion:

1. Opp describes a process for determining whether the concentration of an aldehyde in a test sample is in excess of a predetermined concentration (i.e., "point of interest" as recited in claim 1). A first reaction system

transforms the amount of aldehyde to the predetermined concentration (Abstract). The second reaction systems transforms the remaining aldehyde to a reaction product which is visually detectable, i.e., by producing a color (*id*; col. 1, l. 50 to col. 2, l. 8; col. 2, ll. 22-35; col. 9, ll. 66-68).

2. Opp states:

> The essentially sequential timing of the action of the two reaction systems can be achieved by a variety of means. **If the reaction kinetics of the two reaction systems are such that the first reaction system acts first and goes to completion before the second reaction system has acted to any significant extent, the two reaction systems may be combined simultaneously with the sample at the beginning of the assay**. If the reaction rates of the two reaction systems are essentially the same, the desired sequential timing of the two reaction systems is achieved by providing the reactant or reactants of the second reaction system in a form which slows release of the second reaction system into the reaction medium until the first reaction system has acted completely.

(Opp, col. 3, ll. 17-30; emphasis provided).

3. Opp describes that the second reactant may be added to the reaction system in the form of a tablet to slow the release of the second reactant (see, e.g., col. 3, ll. 34-37).

4. Even when the second reactant is in tablet form during the first reaction of Opp, the first reacting step is "in the presence of" the second reactant, that is, "[e]ach reaction system is present" (see, e.g., Opp, col. 7, ll. 50-65).

Analysis

Applying the preceding legal principles to the factual findings in the record of this appeal, we determine that the Examiner has properly identified

factual findings and reasoning for establishing a prima facie case of anticipation based on Opp which Appellants have not adequately rebutted by the arguments of record.

It is well established that, during examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification. *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

Appellants contend that "the first reaction does not occur in the presence of the second reactant." (Br. 5). Accordingly, we first construe the disputed term "in the presence of" as found in the pertinent clause of claim 1 on appeal. The plain meaning is that the first reacting step occurs while the second reactant is present. We determine that the first reacting step of Opp does indeed occur in the presence of the second reactant, even when the second reactant is in the form of a tablet, and thus meets the disputed claim language (FF 1-4; Ans. 7).

In any event, Opp also explicitly describes a method whereby the reaction kinetics are such that the two reaction systems are combined simultaneously, that is, one does *not* need to provide the second reactant in the form of a tablet (Ans. 7, FF 2).

Appellants' remarks regarding the alleged limited enabling disclosure of Opp (Br. 5) in this regard are not well taken. It is well established that a prior art patent is presumed to be enabling, and that the burden is upon Appellants to provide facts rebutting this presumption. *See, e.g., In re Sasse* 629 F.2d at 680. Appellants have provided no clear and convincing evidence that Opp is not enabling for all the reaction kinetics described therein. *Cf. Spence* 261 F.2d at 261. We further note that Opp teaches that

the same reactants may be used as used by Appellants (e.g., Opp describes hydroxylamine or hydrazine as the first reactant, and lysine or glycine as the second reactant; same as Appellants' claimed reactants of claims 2-5[2] and 6). See e.g., Ans. 4; Opp, col. 4, ll. 15-20, 51-52). This further supports the presumption that Opp is an enabling reference with respect to the reaction kinetics described in Opp (e.g., at col. 3, ll. 17-24).

For these reasons, we agree with the Examiner and determine that the Examiner has established that Opp does describe a method as claimed in claim 1.

Thus, we affirm the Examiner's § 102 rejection based on Opp of claim 1, as well as not separately argued claims 2-7, 10-12, 14 and 30.

*The 103 rejection of dependent claim 13*

Appellants' arguments that there is no suggestion for combining McAlister with Opp are not well taken. Recently, in *KSR Int'l Co. v. Teleflex, Inc.,* the Supreme Court advised that the analysis in support of a conclusion of obviousness need not seek out express teachings that are directed to the subject matter of Appellants' claim since the inferences and creative steps that a person of ordinary skill in the art would have employed can be considered. *KSR,* 127 S. Ct. at 1740-41. One of ordinary skill in the art is also a person of ordinary creativity, not an automaton. *KSR,* 127 S. Ct. at 1742.

Certainly, skill in the art is presumed and based on the collective teachings of the applied prior art we find that one of ordinary skill in the art would have appreciated that using a syringe with "an air permeable, fluid

[2] Note in claim 5 the "second reactant" should be the "first reactant".

impermeable" plug element as taught in McAlister (see, e.g., McAlister abstract)[3] would have achieved the predictable result of ensuring an easily dispensed preset sample for testing in the method of Opp. *Id.* at 1739, 1740. *See also Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1364 (Fed. Cir. 2007) (the expectation of success need only be reasonable, not absolute).

Thus, we agree with the Examiner that the subject matter recited in claim 13 would have been prima facie obvious in view of the combined teachings of Opp and McAlister.

*The 103 rejection of claims 32 and 33*

Appellants do not dispute that the combination of Witonsky and Wu teaches a process for determining whether the concentration of OPA (i.e., *o*-phthalaldehyde) in a test sample is in excess of a predetermined concentration (i.e., "point of interest" as recited in claim 32) using test strips impregnated with a sulfite compound and an amino acid compound, such as glycine (Ans. 6). Wu is cited to explicitly describe the three reactions that take place when using the test strips of Witonsky (*id.*; Wu, col. 2, ll. 31-52).

Appellants' contention that the combination of Witonsky and Wu fails because the claim 32 involves "a two step reaction which the Examiner seeks to find obvious through a three step reaction" (Br. 6) are not well taken. We agree with the Examiner that the claim does not preclude intermediate reaction steps. It is well established that the transitional term "comprising" is "inclusive or open-ended and does not exclude additional,

[3] Compare to "a measuring device having a gas or vapor permeable but liquid impermeable membrane" as recited in claim 13. The measuring device of claim 13 "may be a syringe" as described by Appellants' (Spec. 8:14-19).

unrecited elements or method steps." *Georgia-Pacific Corp. v. United States Gypsum Co.*, 195 F.3d 1322, 1327 (Fed. Cir. 1999). Therefore, Appellant's use of the term "comprising" permits the presence of additional steps, such as the intermediate reaction as taught in Wu to be taking place in Witonsky.

Appellants also contend that since the second reaction forms the sodium glycinate, it follows that the sodium glycinate ("the compound having an amino group" as required in claim 32) is not present during the first reaction. We disagree. We agree with the Examiner's implicit analysis that the claim permits the first reacting step to occur in the presence of both the glycine and/or sodium glycinate (each of these compounds having an amino group as required by claim 32) as the reactions take place, as the teachings of Witonsky and Wu would have suggested.

Certainly, it appears reasonable one of ordinary skill in that art would have readily appreciated that the three reactions of Witonsky's test strip (as described in Wu) would not go to 100% completion in separate sequential fashion. Further, as the Examiner points out, glycine (a compound having an amino acid group, which is subsequently coverted to the sodium glycinate in the second reaction as described in Wu) is present in the first reaction step of Witonsky and Wu (Ans. 6, 8). The Examiner's position is further bolstered by Appellants' own description which includes using the same reactants (i.e., sodium bisulfite and glycine) as the Witonsky and Wu combination (i.e., sodium bisulfite and glycine) in the presence of an aldehyde to be tested.

For all these reasons, the Appellants have not adequately rebutted the Examiner's reasonable position. Thus, we affirm the Examiner's § 103 rejection based on Witonsky and Wu of claims 32 and 33.

## CONCLUSION

In summary, all of the Examiner's rejections are sustained.

The Examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

## AFFIRMED

Ls/cam

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